

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): 10/7/2019



EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-30235
(Commission File Number)

04-3257395
(IRS Employer Identification No.)

**1851 Harbor Bay Parkway
Alameda, California 94502**
(Address of principal executive offices) (Zip Code)

(650) 837-7000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock \$.001 Par Value per Share	EXEL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On October 7, 2019, Exelixis, Inc. (“Exelixis” or the “Company”) announced that it has received a Paragraph IV Certification Notice Letter from MSN Pharmaceuticals, Inc. (“MSN”) that MSN had filed an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) for a generic version of CABOMETYX® (cabozantinib) tablets (20 mg / 40 mg / 60 mg) (the “Notice”).

The Notice states that MSN intends to market a generic version of CABOMETYX before the expiration of Exelixis’ U.S. Patent Nos. 8,877,776, 9,724,342, 10,034,873 and 10,039,757, all of which are listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book (the “Subject Patents”). The Notice does not challenge the CABOMETYX composition of matter patent No. 7,579,473, which expires on August 14, 2026. The Notice alleges that the Subject Patents are invalid, unenforceable and/or will not be infringed by MSN’s commercial manufacture, use or sale or the subject drug products.

Exelixis currently is reviewing the Notice. The Company intends to vigorously enforce its intellectual property rights relating to CABOMETYX, but cannot predict the outcome of this matter. CABOMETYX is protected by six issued patents in the United States, all of which are listed in the Orange Book.

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements related to Exelixis’ intention to vigorously enforce its intellectual property rights. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: risks related to the ability of Exelixis to protect its intellectual property rights and defend its patents; the possible introduction of generic versions of CABOMETYX; Exelixis’ dependence on sales of CABOMETYX; and those other risks discussed under the caption “Risk Factors” in Exelixis’ Quarterly Report on Form 10-Q for the quarter ended June 28, 2019, filed with the Securities and Exchange Commission on July 31, 2019. Exelixis undertakes no duty to update these statements other than to the extent required by applicable law.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EXELIXIS, INC.

October 7, 2019

Date

/s/ JEFFREY J. HESSEKIEL

Jeffrey J. Hessekiel

Executive Vice President and General Counsel

